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July 16, 2004

Dr. Lester Crawford, Acting Director
Food and Drug Administration
5600 Fisher Lane, Rm. 1471
Mail Stop HF-1
Rockville, MD
20857

Dear Dr. Crawford,

I am writing to you to express my concern as a veterinarian and professor in the Department of Avian Medicine over the issue now before you (Docket # 00N-1571) pertaining to the proposed withdrawal of the NADA for Baytril (Enrofloxacin) for use in turkeys and chickens. I am compelled to express my concern that the process has progressed to this point with little or no consideration given to the underlying science in general and specifically to expert testimonies presented by poultry experts in support of Baytril by Bayer, the products sponsor. The ALJ initial decision literally ignored substantial evidence, uncontested in the record, establishing that Baytril is the only alternative available to head off E. coli septicemia and avoid processing very sick animals. It is well known to all who have experience in the poultry industry that processing birds sick with air-sacculitis can cause dramatic increases in fecal contamination and reprocessing, with the end result that food borne pathogens will be more likely transmitted onto final product. Since the passage of the Presidents' Food Safety Initiative in 1996, the same year as Baytril's approval, the poultry industries have made substantial strides in reducing food borne disease organisms; removing Baytril's approval will cause us to step backwards. CDC's reports on disease incidences substantiate that human cases of campylobacteriosis in the U.S. have dropped 47% (from 25.5 to 13.3 per 100,000 residents) since Baytril's approval. I urge you to please weigh these important facts and consider that Baytril's benefits likely far outweigh its risks.

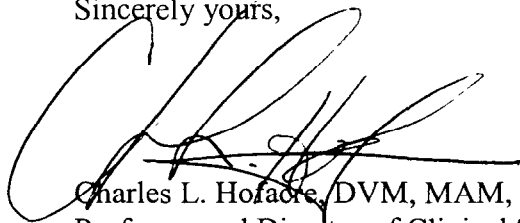
I am equally concerned that CVM and the ALJ would allow this process to involve Baytril's turkey claim when no meaningful evidence was presented to justify removal of the NADA for turkeys. My professional career has given me substantial background in both the chicken and turkey industries and while the *current* evidence for chicken being a source of human Campylobacteriosis is weak and diminishing, it is substantially less for turkeys. It is simply not scientifically justifiable or appropriate to lump the two species together as "poultry".

Baytril is well-controlled under current usage by competent, responsible veterinarians who specialize in poultry disease control and take their food safety responsibility to the public and to their profession very seriously. Our view has always been to preserve the longevity of Baytril by applying Judicious Use Principles as put forth by the AVMA, AAAP, NCC, NTF and others. (Baytril is used in less than 1% of broilers.) I would be honored if you would take the time to read my testimony on this matter (A-202) and that of the other poultry experts.

Dr. Crawford, as one who has always put his trust in the "scientific method" to discover truths, I am amazed and baffled how so many compelling points of science and data have been ignored in the initial ruling of this case, but I trust in your wisdom as you make this important decision.

I hope that you will choose independent reviewers who can give objective, scientific input for the Final Ruling as it appears to me there is still a clear need for this in this proceeding.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'C. Hofacre', written over a horizontal line.

Charles L. Hofacre, DVM, MAM, PhD
Professor and Director of Clinical Services

cc: Food and Drug Administration
Dockets Management Branch
Ref. Docket # 00N-1571
5630 Fishers Lane
Room 1061
Rockville, Maryland 20857